DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01 D-04751

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—ANDAs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—ANDAs." This draft guidance provides information for applicants on how to submit abbreviated new drug applications (ANDAs) in electronic format.

DATES: Submit written or electronic comments'on the draft guidance by [insert *date 60 days after date of publication in* **the Federal Register}.** General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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FOR FURTHER INFORMATION CONTACT: Ruth Warzala, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5845, e-mail: ESUB_OGD@CDER.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—ANDAs." In the Prescription Drug User Fee Act as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by **2002.** In the **Federal Register** of January 28, 1999, the agency announced the availability of two guidances for industry entitled "Providing Regulatory Submissions in Electronic Format—NDAs" (64 FR 4432) and "Providing Regulatory Submissions in Electronic Format-General Considerations" (64 FR 4433). These guidances were the first two of a series of guidances for industry on making regulatory submissions in electronic format. In the 1999 guidance on general considerations, the agency stated that guidance would be forthcoming on other submission types and structured formats, including ANDAs, investigational new drug applications, and product licensing applications. When finalized, this draft guidance should be used in conjunction with the two previously issued guidances (64 FR 4432 and 4433, respectively).

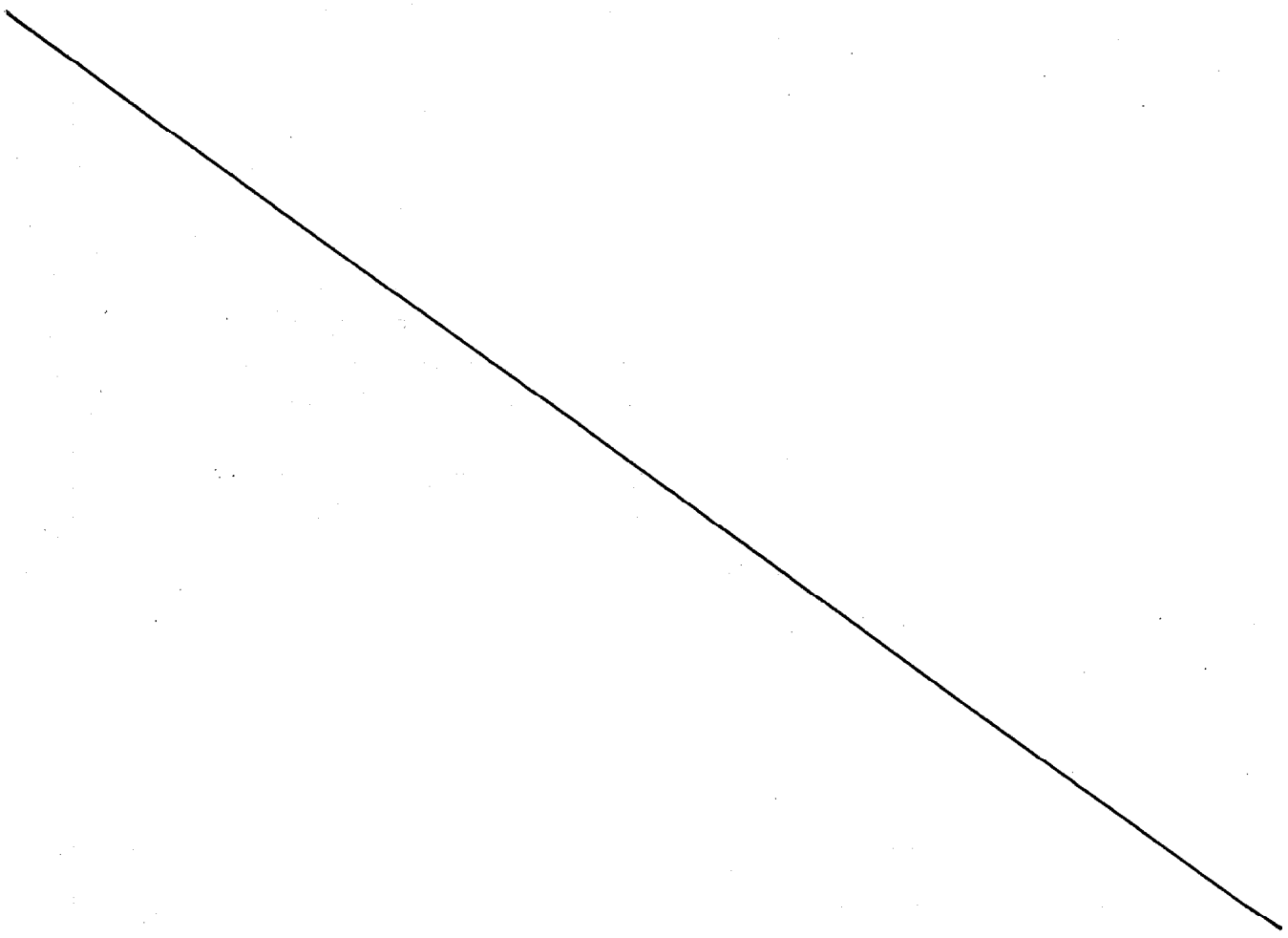
CDER has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these electronic submissions could not previously be archived and could only be made in addition to a complete paper submission. The electronic data submission program is now being expanded to include all parts of ANDA so that the electronic submission can replace the paper submission as the archival copy of ANDA.

This draft guidance is being issued consistent with FDA's good 'guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on providing ANDAs in electronic format. It does not create or confer any rights for or on any

person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 11/7/01
November 7, 2001:

Margaret M. Dotzel,
Associate Commissioner for policy.

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